UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

In re: OXYCONTIN ANTITRUST LITIGATION

This Document Relates To:

Louisiana Wholesale Drug Co., Inc., Civil Action No. 04-CV-00229 (SHS)

Rochester Drug Cooperative, Inc., Civil Action No. 04-CV-00327 (SHS)

Meijer, Inc., Civil Action No. 04-CV-00494 (SHS)

Valley Wholesale Drug Co., Inc., Civil Action No. 04-CV-01014 (SHS)

SAJ Distributors, Inc. Civil Action No. 04-CV-01354 (SHS)

Walgreen, et.al, Civil Action No. 04-CV-01446 (SHS)

Albertson's, et.al., Civil Action No. 04-CV-09649 (SHS)

CVS Pharmacy, Inc and Rite Aid Corporation, Civil Action No. 04-CV-03719 (SHS)

NeighborCare, Inc., Civil Action No. 04-CV-03156 (SHS)

Care Pharmacies, Inc. Civil Action No. 04-CV-3890 (SHS)

Medic Drug, Inc. Civil Action No. 04-CV-04574 (SHS) 04-MDL-1603 (SHS)

ECF CASE

DIRECT PURCHASER CLASS PLAINTIFFS' AND NON-CLASS PLAINTIFFS' JOINT MEMORANDUM IN SUPPORT OF MOTION TO LIFT THE STAY

Direct Purchaser Class Plaintiffs and Direct Purchaser Non-Class Plaintiffs (collectively, "Plaintiffs") bring this Motion respectfully requesting that the Court lift its March 30, 2006 stay of this antitrust litigation.

I. INTRODUCTION

This direct purchaser antitrust litigation has made little forward progress despite its four-year pendency since inception in January, 2004, subsequent to this Court's holding in the *Purdue-Endo* patent litigation that Purdue's OxyContin patents were unenforceable due to inequitable conduct before the United States Patent and Trademark Office ("PTO"). See Purdue Pharma L.P. v. Endo Pharms., Inc., 2004 U.S. Dist. LEXIS 10 (S.D.N.Y. Jan. 5, 2004). That ruling was initially affirmed by the Federal Circuit in February 2005. See Purdue Pharma L.P. v. Endo Pharms., Inc., 410 F.3d 690 (Fed. Cir. 2005).

On January 18, 2006, this Court conducted an Initial MDL Conference to coordinate the progress of the various antitrust class actions, including Plaintiffs' action. Shortly thereafter, on February 1, 2006, the Federal Circuit vacated its prior affirmance in the *Purdue-Endo* patent litigation proceedings and remanded to this Court for further proceedings on the question of enforceability. See Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123 (Fed. Cir. 2006).

On February 9, 2006, Purdue filed a motion to stay all activity in this antitrust litigation pending the issuance of this Court's decision on remand from the Federal Circuit in the patent litigation. Plaintiffs opposed that motion. However, on March 30, 2006, this Court granted Purdue's motion and stayed all activity in this litigation, stating, inter alia, that "[b]ecause disposition of the antitrust issues will be greatly impacted by the determination on remand of the validity of the underlying patent, the Court declines to entertain the antitrust claims at this time." See Multidistrict Litigation Order No. 2 at 2.

The raison d'etre for the stay no longer exists. On January 7, 2008, this Court issued that

¹ Plaintiffs opposed then, as they do now, Purdue's position that this Court's inequitable conduct ruling could be dispositive of Plaintiffs' antitrust claims.

remand decision, determining that Purdue did not engage in inequitable conduct. Accordingly, under the terms of the Order, the time is ripe for the Court to lift the stay and allow this separate antitrust litigation to finally proceed.

Defendant's memorandum in support of the stay suggested—incorrectly—that Plaintiffs' antitrust claims could be mooted by this Court's remand opinion. The law is otherwise.² First, because Plaintiffs are not participants in the *Purdue-Endo* or other patent litigation, this Court's decision in those cases lacks any preclusive effect under the doctrines of res judicata and collateral estoppel. Second, Seventh Amendment protections insulate Plaintiffs against the application of this Court's equitable determination regarding inequitable conduct to Plaintiffs' fact-based claims. Third, even accepting, arguendo, that this Court's equitable determination could be applied to Plaintiffs' jury claims, said claims—including Plaintiffs' scheme claim—are broad enough to survive disposition. And fourth, this Court's January 7, 2008 opinion in the patent litigation contains key errors which critically undermine this Court's ultimate conclusion that Purdue did not engage in inequitable conduct before the PTO. Hence, for all of the foregoing reasons, Plaintiffs' antitrust claims are not mooted by the current posture of the patent litigation.

Accordingly, Plaintiffs respectfully request that the Court enter an Order lifting the stay.

II. ARGUMENT

The Time is Ripe for Plaintiffs' Antitrust Claims to Proceed A.

Now that the Court has issued its inequitable conduct decision, there is no longer any

² Interestingly, Purdue noted in both its moving and reply papers requesting the stay that the antitrust claims should proceed once the inequitable conduct questions were resolved. See Purdue Mem. Of Law in Support of Mot. to Stay at 4 ("Purdue submits that the Court should stay any further proceedings in this docket pending a further decision by this Court in the Endo patent litigation."); Purdue Reply Mem. in Support of Mot. to Stay at 3 ("[T]he appropriate course is to await a further decision in the *Endo* patent litigation.")

procedural impediment to Plaintiffs' cases moving forward in an expeditious manner. As aforementioned, this litigation was filed over four years ago, yet as a result of the stay Plaintiffs have been largely unable to proceed in any meaningful manner, causing Plaintiffs prejudice, and any continued delay will only compound that prejudice.³

Although Purdue has made past attempts to portray the merits of Plaintiffs' antitrust claims as turning on the outcome of the inequitable conduct defense in the patent litigation, (see Purdue's Mem. of Law in Support of Purdue's Mot. for Stay), the plain fact remains that Plaintiffs' antitrust suit is wholly separate and independent from the patent litigation. Plaintiffs are not parties to the patent litigation and have never participated in that litigation in any manner. As such, Plaintiffs are not bound by any decisions in that litigation, including this Court's January 7, 2008 opinion, under well-established principles of collateral estoppel. See, e.g., Burt v. Gates, 502 F.3d 183, 188 n.5 (2d Cir. 2007).

Furthermore, Plaintiffs are entitled to prosecute their claims before a jury. In patent infringement cases, inequitable conduct is an issue reserved for the court rather than a jury. See Paragon Podiatry Labs., Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1190 (Fed. Cir. 1993); PerSeptive BioSystems, Inc., v. Pharmacia Biotech, Inc., 225 F.3d 1315, 1318 (Fed. Cir. 2000) ("The defense of inequitable conduct is entirely equitable in nature, and thus not an issue for the jury to decide."). Hence, this Court properly chose to resolve the inequitable conduct defense itself in the patent litigation.

Conversely, in an antitrust case it is a jury who decides whether a defendant has committed the acts constituting the restraints of trade that violate the antitrust laws. See, e.g., Unitherm Food

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³ For instance, Plaintiffs could have engaged in discovery during the two years in which the stay has been operative.

Sys. v. Swift-Eckrich, Inc., 546 U.S. 394, 397 (2006) (discussing a Walker-Process jury verdict). Indeed, the highly factual issues of intent and materiality raised by a Walker-Process claim are quintessential jury questions. See Poller v. Columbia Broadcasting Sys., Inc., 384 U.S. 464, 473 (1962) (antitrust decision indicating that a jury should resolve issue of intent); Pacific Indem. Co. v. Golden, 985 F.2d 51, 57 (2d Cir. 1993) (materiality of party's statements is an issue to be decided by a jury).

Indeed, the United States Supreme Court has unequivocally stated that a party's right to a jury trial for antitrust claims of a legal – rather than equitable -- nature "cannot be dispensed with ... nor can [they] be impaired by" a claim involving equitable relief. See Beacon Theatres, Inc. v. Westover, 359 U.S. 500 (1959) ("[O]nly under the most imperative circumstances, circumstances which in view of the flexible procedures of the Federal Rules we cannot now anticipate, can the right to a jury trial of legal issues be lost through prior determination of equitable claims.") Accordingly, unlike the patent defendants advancing their defense of inequitable conduct, Plaintiffs are clearly entitled to pursue their antitrust claims with the full benefit of a jury trial.⁴

Moreover, Plaintiffs' right to a jury trial is of particular relevance here. As detailed below, Plaintiffs respectfully assert that various errors exist in this Court's January 8, 2008 opinion which undermine its conclusion that Purdue did not commit inequitable conduct before the PTO, and because those errors pertain to issues that exist in this litigation, Plaintiffs are entitled to put forth their own record before a jury.

В. Plaintiffs' Antitrust Claims Are Not Mooted by This Court's Recent Decision in the Patent Litigation; That Decision Contains Critical Errors Which Undercut This Court's Conclusion That Purdue Did Not Engage in Inequitable Conduct before the

⁴ Moreover, Plaintiffs have alleged that Purdue engage in a scheme to delay generic entry, for which they are entitled to a jury trial.

PTO

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Even if this Court were to accept, *arguendo*, Defendants' suggestion that this Court's finding that Purdue did not engage in inequitable conduct before the PTO is dispositive of Plaintiffs' antitrust claims, Plaintiffs respectfully submit that this Court's January 8, 2008 Opinion contains fundamental errors which undermine that holding.

Specifically, Plaintiffs respectfully assert that there are four areas as to which either: (a) the Court made erroneous statements and/or conclusions pertaining to the prosecution and issuance of Purdue's OxyContin patents; or (b) the infringement defendants failed to put forth the necessary evidence (as Plaintiffs plan to here) that would have led the Court to materially different conclusions. Accordingly, Plaintiffs respectfully submit that the Court's ultimate conclusion of no inequitable conduct constitutes reversible error.

1. Erroneous Statements Regarding the Type of Evidence Purdue Was Required to Put Forth in Response to the PTO's Obviousness Rejection

Plaintiffs respectfully assert error with respect to the following statements in this Court's January 8, 2008 opinion ("Op."):

- "Purdue's ability to obtain patents for its OxyContin formulations did not turn on whether the discovery of a reduced dosage range was a product of insight or experimentation." (Op. at 9).
- "Economic pressure to obtain a patent would not, as a matter of logic, prompt an applicant to characterize a discovery obtained by insight as one derived through experimentation because both types of discoveries are equally patentable." (Op. at 9-10).

Purdue does not contest that "the discovery of OxyContin's reduced dosage range was based solely on Dr. Kaiko's 'insight'" (Op. at 6). The Federal Circuit held — and Plaintiffs do not dispute here — that a "discovery" may be based on "insight" rather than experimentation. <u>Purdue</u>, 438 F.3d at 1132-33. Thus, Purdue's lack of empirical evidence did not preclude patentability at

the outset of the prosecution of the '331 Patent. However, Purdue's obligation to supply empirical evidence changed markedly during the prosecution of the '331 Patent.

"During examination, the examiner bears the initial burden of establishing a *prima facie* case of obviousness. The *prima facie* case is a procedural tool, and requires that the examiner initially produce evidence sufficient to support a ruling of obviousness..." In re Kumar, 418 F.3d 1361, 1366 (Fed. Cir. 2005) (internal citation omitted). Absent a prima facie obviousness rejection, Purdue would have been "under no obligation to submit evidence of nonobviousness." MANUAL OF PATENT EXAMINING PROCEDURE (8th Ed. Sept. 2007 revision)("MPEP") § 2142 (attached as Exhibit A to the February 21, 2008 Declaration of Bruce E. Gerstein (the "Gerstein Dec.")) at 2100-127.⁵ Had the Examiner of the '331 Patent failed to mount a prima facie obviousness rejection, Purdue's lack of empirical data for OxyContin would not have been relevant.

However, the Examiner did issue a *prima facie* obviousness rejection. See Office Action dated April 30, 1992 (Exhibit B to the Gerstein Dec.). Once this occurred, circumstances changed—most importantly, the burden shifted to Purdue to submit objective evidence of nonobviousness, such as evidence of surprising or unexpected results. In re Kumar, 418 F.3d at 1366. Where *prima facie* obviousness exists, the failure of an applicant to provide rebuttal evidence

⁵ "The Manual of Patent Examining Procedures ("MPEP"), promulgated by the PTO, sets forth practices to be followed by patent applicants and PTO processes of which they should be aware, pursuant to the duty of candor. While the MPEP does not constitute binding law, it has received judicial notice as an official interpretation of patent law. In an inequitable conduct dispute, moreover, the MPEP serves as a common articulation of patenting norms, indicating what information is appropriately considered material and reflecting on the intentions of an applicant who does not follow it. Thus, while a violation of standards set forth in the MPEP does not ipso facto constitute sufficient proof of inequitable conduct, courts appropriately take note of it as evidence of what a reasonable patent examiner would consider material." Eisai Co., Ltd. v. Dr. Reddy's Laboratories, Ltd., No. 03 civ. 9053, 2007 WL 1437834, *21 n. 14 (S.D.N.Y. May 14, 2007) (internal citation omitted).

is "dispositive." MPEP 716.01(a) (Exhibit C to the Gerstein Dec.) at 700-290. Importantly, "[a]n applicant cannot prove unexpected results . . . without <u>objective evidentiary support</u>." <u>CFMT, Inc. v. Yieldup Int'l Corp.</u>, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (emphasis added); <u>In re Be Blauwe</u>, 736 F.2d 699, 705 (Fed. Cir. 1984) ("It is well settled that unexpected results must be established by factual evidence.") Thus, while empirical evidence regarding OxyContin was not required at the outset of prosecution, the situation changed drastically after the PTO examiner issued a *prima facie* obviousness rejection during the prosecution of the '331 Patent, thereby requiring Purdue to rebut the *prima facie* case.

Consistent with its recognition that "factual evidence" would be required to establish "surprising results," Purdue responded to the *prima facie* obviousness rejection by arguing the "surprising result" and clinical significance of the invention under headings containing the phrases "Surprisingly Improved Results." See Office Action Response dated October 22, 1992 (Exhibit D to the Gerstein Dec.) at 3 & 5. This Court has previously recognized that Purdue "relied heavily on its discovery of the reduced dosage range to support its arguments for patentability." (Op. at 6-7). While Purdue initially relied on only Dr. Kaiko's alleged "discovery," after the prima facie obviousness it shifted to "Surprisingly Improved Results." An interview took place between the PTO examiner and Purdue's counsel on February 25, 1993. See Examiner Interview Summary dated February 25, 1993 (Exhibit E to the Gerstein Dec.). At that interview, the participants agreed that Purdue would submit a declaration "supporting...unexpected results." <u>Id.</u> Shortly thereafter, Purdue submitted Dr. Kaiko's declaration (Exhibit F to the Gerstein Dec.). Dr. Kaiko's sworn declaration was central to establishing "surprising results" for the '331 Patent —and to the later patents whose prosecutions were thereby affected—because "[o]bjective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes

evidence of unexpected results..." MPEP 716.01(c) (Exhibit G to the Gerstein Dec.) at 700-290. The MPEP demands such evidence in declaration form as an "assurance[] that any statements or representations made are correct, as provided by 35 U.S.C. 25 and 18 U.S.C. 1001." MPEP 716.02(g)(Exhibit H to the Gerstein Dec.) at 700-297.

Absent Purdue's misrepresentation that empirical data existed, the examiner would not have withdrawn his obviousness rejection. Indeed, as this Court has already recognized, "the patent examiner considered these statements 'decisive' in allowing at least one of the patents-in-suit—the '042 patent—to issue." (Op. at 7). The Federal Circuit never found fault with that statement. To the contrary, the Federal Circuit specifically noted that "Purdue's assertion of a four-fold dosage range for oxycodone and more efficient titration process compared to other opioids . . . was one of the key arguments Purdue made consistently and repeatedly during prosecution to overcome prior art cited by the examiner in an obviousness rejection." Purdue Pharma L.P., 438 F.3d at 1132. The simple fact is that Purdue's arguments were necessarily founded on an affirmative misrepresentation that data existed because, absent such data, Purdue's arguments would not have been meaningful in responding to the PTO rejection. In re De Blauwe, 736 F.2d 699, 705 (Fed. Cir. 1984) ("It is well settled that unexpected results must be established by factual evidence.").

2. Erroneous Conclusions Regarding the Adequacy of the Data Regarding the Difference in Dosage Ranges Between OxyContin and MS Contin

Plaintiffs do not concede, as the generic defendants apparently did, the points below from this Court's Opinion:

- "It is undisputed that Purdue had adequate data to claim that the opioid morphine required an eight-fold dosage range for ninety percent of patients." (Op. at 11).
- "That [1989 Kaiko] article, as defendants concede, provides sufficient support for Purdue's claim that surveys existed with respect to at least one opioid, morphine." (Op. at 11).

Central to Purdue's patentability assertions was the purportedly much narrower dosage range for OxyContin relative to other opioids. According to Purdue, OxyContin surprisingly exhibited a four-fold dosage range for the treatment of 90% of patients whereas other opioids required an eightfold dosage range. The magnitude of this allegedly unexpected difference—a factor of two between OxyContin and other opioids—was central to the prosecution of the Purdue patents. Purdue Pharma L.P., 438 F.3d at 1130 ("Purdue continued to rely on oxycodone's four-fold dosage range and more efficient titration process to support its patentability arguments throughout prosecution of the '331 patent.")

The 1989 Kaiko Article⁶ (Exhibit I to the Gerstein Dec.) on which this Court relied in its recent Opinion undercuts, rather than supports, Purdue's dosage range representations to the PTO. Had the Examiner been in possession of and appreciated the 1989 Kaiko Article, he would not have accepted Purdue's representation of a two-fold difference in dosage range between OxyContin and other opioids because the 1989 Kaiko Article supports the view that the dosage ranges for OxyContin and MSContin are much closer than two-fold. Further, the 1989 Kaiko Article undercuts Purdue's present assertion that MSContin exhibits an eight-fold dosage range and instead suggests a dosage range much closer to OxyContin.

The 1989 Kaiko Article presents, as Figure 2, a bar chart depicting the MSContin doses administered to 218 patients who participated in the study. Exhibit I at 2350. According to Plaintiffs' reading of the bar chart: (1) 75 out of 218 patients were administered from 60-90 mg morphine; (2) 98 out of 218 patients were administered 120-240 mg morphine; (3) 33 out of 218

⁶ The United States Experience With Oral Controlled-Release Morphine (MS Contin Tablets). Parts I and II. Review of Nine Dose Titration Studies and Clinical Pharmacology of 15-mg, 30-mg, 60-mg, and 100-mg Tablet Strengths.

patients were administered 270-480 mg morphine; and (4) 12 out of 218 patients were administered >480 mg morphine. The bar chart thus reflects that 79.4% (173 out of 218) of the patients were treated with a four-fold dosage range (60-240 mg) of MS Contin (i.e., morphine). This figure of course compares quite closely with the 84.4% of patients who this Court found were treated using a four-fold dosage range of OxyContin (*i.e.*, oxycodone) (see Purdue, 2004 U.S. Dist. LEXIS at *47-48) and undercuts any allegation by Purdue that the dosage ranges for OxyContin and MS Contin were two-fold (or even close to two-fold) different. Furthermore, according to the 1989 Kaiko Article, the percentage of patients treated over an eight-fold range with MSContin was 94.5% (206 out of 218 patients), well more than 90%, confirming that the dosage range for treating 90% of patients with MS Contin is in fact less than eight-fold.⁷ Even assuming *arguendo* that Purdue possessed evidence that morphine exhibited an eight-fold dosage range—which it did not—Plaintiffs assert error with respect to the following statement in the Court's opinion:

During the prosecution of the parent patent Dr. Kaiko informed the PTO that he considered morphine to be the "prototypic opioid analgesic." (PTX 7 at '331-59.) It would have been wholly consistent with that view for Dr. Kaiko to draw conclusions about the properties of opioids generally based on what is "suggested" by the surveys of morphine that he considered representative of the entire class of opioids. (Op. at 12).

Throughout the course of the prosecution of its patents, Purdue relied on the inherent unpredictability of opioids and the inability to extrapolate findings from one opioid to another. Indeed, this Court cited to many such assertions by Purdue in its Opinion:

• "Purdue responds that indeed it was surprising for OxyContin to exhibit these properties

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⁷ While a 4.5% difference may seem small in absolute terms, the maximum possible difference in moving from 90% of patients to 100 % of patients is 10%. Further, to the extent the Court deems small a 4.5% difference, the Court must necessarily deem small the 5% difference between the percentage of patients treated with a four-fold dosage range of MS Contin (79.4%) and the percentage of patients treated with a four-fold dosage range of OxyContin (84.4%).

because all opioids are different and one cannot infer that the pharmacokinetic was pharmacodynamic properties—such as tmax and duration of activity—exhibited by a formulation of one opioid will arise in a similar formulation of another opioid." (Op. at 18-19).

- "Purdue maintains that even when similar in vitro results between opioids are obtained, one cannot assume that the in vivo results will be the same." (Op. at 19).
- "Dr. Kaiko advanced two relevant observations. First, he stated that "one skilled in the art having information concerning the time to reach peak plasma concentration ["tmax"] and duration of effect" for one controlled-release opioid formulation "could not predict whether a controlled-release oxycodone formulation having tmax in 2 - 4 hours would also provide duration of therapeutic effect of at least 12 hours." (Id. at '331-54 (emphasis in original).) Second, Dr. Kaiko stated that "[o]ne cannot infer that in vitro release characteristics of a formulation for a particular drug giving rise to certain in vivo peak plasma levels and duration of activity . . . will provide the same duration of activity for another drug." (Id. (emphasis in original).)" (Op. at 19).
- "In further support of the purported fallacy of extrapolating from one opioid to another and inferring that similar in vitro characteristics of two opioids necessarily implies similar in vivo characteristics, Purdue refers the Court to the 1992 American Pain Society publication noted above, which states in relevant part that "individual patients respond differently to different opioids."" (Op. at 19).

Purdue cannot reasonably argue that the performance of OxyContin was inherently unpredictable for purposes of justifying its alleged "surprising" results while at the same time arguing that the performance of other opioids was inherently predictable for purposes of justifying its decision to extrapolate the performance of the other opioids from morphine.

3. This Court Erroneously Discounted Key Clinical Data.

This Court erroneously discounted the Reder survey because "titration was not actually tested in those studies" and, consequently, "any opinions the Reder survey respondents may have expressed concerning the ease of titration could not have been based on any actual experience with titrating OxyContin." (Op. at 15). According to the Court, "the Reder Survey's findings were not grounded in relevant data and therefore immaterial to Purdue's claim that OxyContin's reduced dosage range would ease titration." (Op. at 15). In reaching this conclusion, the Court necessarily adopted a contradiction: namely, that an examiner would blindly credit Dr. Kaiko's "surprising discovery" based purely upon his mental insight rather than relevant data, while at the same time blindly discounting the views of Dr. Kaiko's contemporaries as based on insight rather than relevant data. Respectfully, this makes no sense. An examiner who appreciated that Dr. Kaiko's "surprising discovery" was based on pure insight would be equally interested in the insight of Dr. Kaiko's fellow scientists, particularly where it contradicted Dr. Kaiko's purported insight.

In concluding that "neither [the Kalso Study nor the LoRusso Study] actually examined ease of titration," this Court necessarily discounted statements in both studies suggesting that titration times were similar, rather than surprisingly different, between OxyContin and MS Contin. For example, the LoRusso Study stated explicitly that "[d]ose titration was accomplished with equal facility with both oral CR [morphine and oxycodone] formulations." (See Mucci-LoRusso et al., 1998, Eur. J. of Pain, Abstract, "Controlled-release oxycodone compared with controlled-release morphine in the treatment of cancer pain: a randomized, double-blind, parallel-group study") (Exhibit J to the Gerstein Dec.) at 246. The Court concluded that "Defendants have not provided this Court with a sound basis to reconsider its prior determination that these studies do not bear on OxyContin's reduced dosage range and, by implication, the corresponding ease of titration." (Op. at 17). While Plaintiffs fully intend to provide this Court with a sound basis for reconsidering its prior determination, Plaintiffs are entitled in any event to present these issues to a jury.

4. This Court Was Not Provided Key Scientific Evidence

This Court found that the generic defendants "have not met their burden of showing that it was a misrepresentation for Purdue to characterize its discovery [that OxyContin afforded 12-hour pain relief despite reaching a peak plasma concentration in just two to four hours] as 'surprising." (Op. at 20). In doing so, this Court credited Purdue's "unchallenged evidence" that opioids are so

unpredictable that OxyContin's T_{MAX} remained a surprise despite an unbroken string of twelve-hour controlled-release opioid formulations having a T_{MAX} between two and four hours. (Op. at 20). According to the Court, the Generic Defendants "do not offer any contrary scientific evidence, showing, for example that new opioid formulations become more predictable as the number of prior successful formulations increases." (Op. at 20). Plaintiffs here intend to offer proof that, given its numerous experiences with other controlled release opioids, a party in Purdue's shoes could not reasonably be surprised by its T_{MAX} finding with respect to OxyContin. Equally important, Plaintiffs intend to prove that subjectively, Purdue was not in fact surprised.

III. CONCLUSION

For the reasons set forth above, Direct Purchaser Class and Non-Class Plaintiffs respectfully request that the Court enter an Order lifting its March 30, 2006 Order staying this litigation.

Date: February 22, 2008

Respectfully submitted,

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